

REMARKS

The advisory action mailed on July 24, 2003 states that the “rejection under 103 is maintained.” Accordingly, Applicant believes that the Section 112 rejections made in the final office action mailed June 9, 2003 have been withdrawn, and that this response must address only the sole rejection under 103.

Claims 26-37, 40-42 and 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,503,765 (Schepers, *et al.*) and U.S. Patent No. 5,268,003 (Coope, *et al.*).

Schepers discloses a non-aqueous liquid composition of dipercarboxylic acids that have low solubility in the non-aqueous liquid. The dipercarboxylic acids disclosed by Schepers are mono- or di-percarboxylic amido or imido acids. (Schepers, col. 8, ln. 43-45). These compounds are high molecular weight compounds and Schepers does not disclose their solubility in water. However, because of their high molecular weight, these compounds disclosed by Schepers would not be considered to be soluble in water at concentrations high enough to form a sterilizing solution. This is confirmed by Coope, the secondary reference, saying that “detergent formulations containing a peroxyacid bleach system ... will usually also contain surfactants ... [that] function as a structuring system to suspend the water-insoluble amido peroxyacids in water or any other solvent carrier.” (Coope, col. 5, ln., 44-50).

Applicant believes that the Examiner has cited *In re Thuau*, 57 USPQ 324 for the law that a new use for an old composition does not render the old composition patentable. Applicant agrees.

However, Applicant asserts that certain limitations in the pending claims make the claims distinguishable over the cited references by much more than a mere statement of the intended use of an old composition. It is these limitations that place the claims beyond the reach of the ruling of *In re*

Thuau. In other words, *In re Thuau* is not dispositive here, because the patentability of the claims does not rest upon a mere new use of an old composition, but rests upon a new and nonobvious composition.

In the case of *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003), the Court of Appeals for the Federal Circuit discussed the patentability of claims to a metabolite DCL in light of a prior art patent disclosing the drug loratadine. Evidence showed that there was no express disclosure of DCL and no mention of the metabolites of loratadine in the prior patent, yet DCL was necessarily formed as a metabolite by carrying out the process disclosed in the earlier '233 patent. After holding that the inherent result of administering loratadine to a patient is the formation of DCL, the Court went further to provide guidance to Applicants for properly claiming inventions when "bare compound claims" are unpatentable.

The Court advised that:

A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed in its pure and isolated form, as in Kratz and Bergstrom, or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). ... The '233 patent would not provide an enabling disclosure to anticipate such claims because, for instance, the '233 patent does not disclose isolation of DCL.

Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003)

Applicant asserts that its present claims are drafted consistent with the foregoing advice of the Federal Circuit, because independent claim 26 is not directed to bare dipercarboxylic acids, but to a combination of components in a measured amount and substantially free from other organic compounds. Applicant is not claiming an old composition as dealt with by *In re Thuau*, but instead is claiming a combination of components including an exothermic control agent. The Schepers and Coope patents do not suggest any need for an exothermic control agent as in the presently claimed

composition. Reconsideration and withdrawal of the rejection is requested.

Schepers does not disclose a solid particulate composition, but rather discloses a non-aqueous liquid composition of dipercarboxylic acids that have low solubility in the non-aqueous liquid. The dipercarboxylic acids disclosed by Schepers are mono- or di-percarboxylic amido or imido acids. (Schepers, col. 8, ln. 43-45). These compounds are high molecular weight compounds and Schepers does not disclose their solubility in water. However, because of their high molecular weight, these compounds disclosed by Schepers would not be considered to be soluble in water at concentrations high enough to form a sterilizing solution. This low water-solubility is confirmed by Coope, the secondary reference. (Coope, col. 5, ln., 46-50).

Applicant claims, *inter alia*, dipercarboxylic acids that may be stored as a solid at room temperature and that are soluble in water to form an aqueous solution having a concentration of at least 0.1 wt. %. (claim 26). The 0.1 wt % concentration is a concentration that is high enough to form a sterilizing solution.

Schepers does not disclose, teach, suggest or motivate that the high molecular weight peracid compounds that are discussed therein may be dissolved in water at a concentration of at least 0.1 wt. %. Schepers discloses solubility of various compounds in non-aqueous solutions, but not in aqueous solutions as claimed by Applicant. (Schepers, col. 12 – col. 14). Schepers discloses peroxyacid concentrations of between 0.1 to 10%, but these concentrations are not in an aqueous solution. Rather, the peroxyacids are “substantially insoluble” (Schepers, col. 3, line 57) in the non-aqueous liquid composition of the Schepers’ invention. (Schepers, col. 4, ln. 30-31). Therefore, Schepers does not teach, suggest or motivate that there exists dipercarboxylic acids that are a stable solid and that can be solubilized in water to form a sterilizing solution as claimed by Applicant.

To establish a *prima facie* case of non-obviousness, there must be (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one having ordinary skill in the art, to modify or to combine reference teachings; (2) a reasonable expectation of success; and (3) all the limitations of the claimed invention disclosed. See MPEP, § 2143.

Schepers does not teach, suggest, motivate or disclose that a dipercarboxylic acid may be stored as a solid and then solubilized in water to form a sterilizing solution having a concentration of at least 0.1 %. In fact, the acids disclosed by Schepers are all high molecular weight acids that are not soluble in water at high enough concentrations to achieve a 0.1 % concentration as claimed by Applicant. Therefore, Schepers does not present a *prima facie* case of obviousness against Applicant's claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Coope discloses the same high molecular weight acid types as Schepers. Coope specifically states that the acids disclosed therein are not soluble in water. Coope states, "When in liquid form, the surfactants serve not only to clean but importantly function as a structuring system to suspend the water-insoluble amido peroxyacids in water or any other solvent carrier." (Coope, col. 5, ln., 46-50). Since the acids disclosed by Coope are not water soluble, Coope does not disclose, teach or suggest a dipercarboxylic acid that is soluble in water at concentrations sufficient to form a sterilizing solution as claimed by Applicant. (claim 26).

Because neither Coope nor Schepers disclose, teach, or suggest a dipercarboxylic acid that is soluble in water at sterilizing concentrations, a *prima facie* case of obviousness has not been presented. Indeed, both Coope and Schepers disclose high molecular weight acids that are not soluble in water, as stated by Coope.

Applicant believes that the Examiner must give full consideration to the functional limitations of the claim when determining obviousness. Functional limitations should be given patentable weight when the function limitations are nonobvious over the prior art. See *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Here, claim 26 includes the limitation of “one or more dipercarboxylic acids that are solid at room temperature and soluble at sterilizing concentrations in water.” The compounds of this limitation are limited by their chemical class, i.e., dipercarboxylic acids, and are further limited to only those dipercarboxylic acids that function to form a “solid at room temperature” and that are “soluble at sterilizing concentrations in water.” These functional limitations are neither disclosed nor suggested by Schepers or Coope. Reconsideration and withdrawal of the rejection is requested.

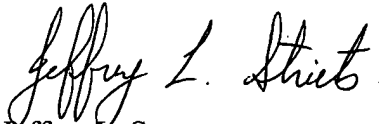
Attention is drawn to claim 31, which claims only a certain six C5 to C9 dipercarboxylic acids and combinations thereof. By contrast, Schepers says that “[t]he peroxyacids used in the compositions of the invention are amide or imide peroxyacids . . .” (Schepers, col. 3, lines 8-9). Coope discloses “a new series of amido-type peroxycarboxylic acids.” (Coope, col. 2, lines 43-44). Applicant asserts that there is no disclosure of the claimed C5-C9 dipercarboxylic acids, and that there is no suggestion to modify the teaching of Schepers or Coope to use these acids. An indication of the allowability of claim 31 is requested.

Applicant has submitted new claims 45-49. Claims 47 and 48 are directed to diperglutaric acid. For the same reasons stated in the previous paragraph, the cited references do not disclose or suggest the use of diperglutaric acid. Claim 49 states that “the one or more dipercarboxylic acid includes less than about 0.1 percent by weight of amido or imido peroxyacids.” While this limitation is not set out in the specification, an applicant may excise the prior art from the claim and still satisfy the written description requirement of section 112, first paragraph. *In re Johnson*, 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977). It is for the inventor to decide what bounds of protection she

will seek and it is perfectly legitimate for an inventor to simply claim less than the full scope of her disclosure. Therefore, Applicant asserts that claim 49 does not introduce new matter into the application and that claim 49 merely excises the subject matter of Schepers and Coope. An indication of the allowability of claims 45-49 is requested.

In conclusion, Applicant submits that all remaining claims in the present application are entitled to allowance and such action is earnestly solicited. In the event there are additional charges in connection with the filing of this Response, the Commissioner is hereby authorized to charge the Deposit Account No. 50-0714/LYNN/0120.A of the firm of the below-signed attorney in the amount of any necessary fee.

Respectfully submitted,



Jeffrey L. Streets
Attorney for Applicant
Registration No. 37,453
STREETS & STEELE
13831 Northwest Freeway, Suite 355
Houston, Texas 77040
(713) 939-9444

CUSTOMER NO. 24945

PATENT TRADEMARK OFFICE